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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/416,384	10/12/99	BLUMENFELD M	GENSET.045AU

020995 HM22/0725
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EXAMINER	
FREDMAN, J	
ART UNIT	**PAPER NUMBER**
1655	8

DATE MAILED: 07/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/416,384	Blumenfeld et al
Examiner	**Group Art Unit**
Jeffrey Fredman	1655

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-57* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-57* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-24, 50, drawn to nucleic acids, vectors and host cells, classified in class 536, subclass 23.1 and class 435, subclasses 240.2 and 320.1.

II. Claims 25-27, drawn to transgenic animals, classified in class 800, subclass 2.

III. Claims 28-44, 47-49, drawn to methods of genotyping, classified in class 435, subclass 6.

IV. Claims 45 and 46, drawn to polypeptide and antibody, classified in class 530, subclasses 300 and 387.1.

V. Claims 51-57, drawn to computer data and computerized methods of analysis, classified in class 720, subclass 19.

2. The inventions are distinct, each from the other because of the following reasons: Inventions in Group I and in Groups II, III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acid products can be used in methods of Genotyping of Group II, in methods of making transgenic animals of Group III or in

computerized analytic methods of Group V or in nucleic acid purification, antisense therapy or gene therapy methods.

3. Inventions in Group I and in Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, because the Group I product is drawn to nucleic while Group IV is drawn to proteins. These products have different modes of operation since nucleic acid methods utilize nucleic acid hybridization while protein methods use protein-protein binding. Further, they have different effects since nucleic acid methods yield information regarding the presence or absence of nucleic acids and protein methods yield information regarding the status of the proteins. Finally, the proteins and nucleic acids themselves represent structurally different molecules with different chemical characteristics, different methods of making and using and different functions and effects.

4. Inventions in Groups II, III, IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions differ in mode of operation, function and effect. Each of these Groups has its own effect with the genotyping method yielding a genotype, the computerized products and methods yielding computer data, the protein useful in protein analysis methods and the transgenic animal yielding a transgenic animal product useful as a model system.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. These claims are generic to a plurality of disclosed patentably distinct species comprising different SEQ ID NOs. Applicant is required under 35 U.S.C. 121 to elect no more than 10 disclosed species representing 10 different SEQ ID NOs even though this requirement is traversed.

This species requirement is based upon the notice in the Official Gazette in October 1996 which states, "Applications claiming more than ten (10) individual independent and distinct nucleotide sequences in alternative form, such as set forth in example 1, will be subject to a restriction requirement. Only the ten (10) nucleotide sequences selected in response to the restriction requirement and any other claimed sequences which are patentably indistinct therefrom will be examined."

Should applicant traverse on the ground that some or all of the different nucleic acid species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. A telephone call was made to Daniel Hart on July 12, 2000 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff Fredman, Ph.D. whose telephone number is (703) 308-6568.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Group 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Jeffrey Fredman
Primary Patent Examiner
Art Unit 1655

July 24, 2000